

### **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The new and amended claims are fully supported by the present specification, particularly at paragraphs [0012] and [0013], for example, and clarify that the invention is directed to a gradient layering of two or more differing molecular weight polymers coated on at least a portion of a surface of an implantable medical device, wherein the differing molecular weight polymers are selected to controllably affect the releasability of said at least one pharmaceutical compound.

The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

#### **35 U.S.C. §103 Rejection**

Claims 1-3, 6-8, 12-16, 18-20, and 23 were rejected under 35 USC 103(a) as being unpatentable over Kamath et al. (WO 2000/32255) in view of Siepmann et al. (“Understanding and Predicting Drug Delivery” Pharmaceutical Research, Vol. 19, No. 3, pages 306-314), further in view of Shwarz (U.S. Pat. No. 6,368,658). This rejection is respectfully traversed.

Siepmann et al. disclose a mathematical model of a tablet as it hydrates and dissolves. There is no teaching or suggestion that this model correlates to implantable medical devices and the delivery of pharmaceutical agents from implantable medical device. In fact, in the Conclusions of the Siepmann et al. article, the authors themselves are only willing to apply the model to tablet designs: “The model is applicable to a wide range of polymers, drugs, release media and tablet compositions, and can be used to understand the effect of the tablet design (e.g., initial radius, height and size) . . .” (emphasis added). Furthermore, the authors themselves warn that “[t]he observed phenomena when varying the device geometry are not straightforward . . .” (emphasis added). Thus, it is respectfully submitted that the teachings of this document cannot be extrapolated beyond tablets (oral controlled drug delivery systems), which does not include implantable medical devices. Therefore, this rejection must fail.

There is no teaching or suggestion of an implantable medical device directed to a gradient layering of two or more differing molecular weight polymers coated on at least a portion of a surface of an implantable medical device, wherein the differing molecular weight polymers are selected to controllably affect the releasability of said at least one pharmaceutical compound.

### **Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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